

Title: A Phase 3, Randomized, Double-Blind, Placebo-Controlled, Multicenter Study of Aztreonam for Inhalation Solution (AZLI) in a Continuous Alternating Therapy (CAT) Regimen of Inhaled Antibiotics for the Treatment of Chronic Pulmonary *Pseudomonas aeruginosa* Infection in Subjects with Cystic Fibrosis.

Principal Investigator: Brian O'Sullivan, M.D.

Sponsor: Gilead Sciences, Inc.

Purpose of Research

The purpose of this research is to see how safe and effective AZLI (Aztreonam for Inhalation Solution) alternating with TIS (Tobramycin Inhalation Solution) compares to placebo alternating with TIS to treat CF patients with chronic *PA* infection. *Pseudomonas aeruginosa* (*PA*) is a bacteria that is difficult to eliminate completely with antibiotics, it can cause lung damage directly and can also increase inflammation in the lungs.

This research study will involve two drugs. The first one is named Aztreonam for Inhalation Solution (AZLI). The FDA has approved AZLI under the name Cayston® for treating *Pseudomonas aeruginosa* (*PA*) infections in patients with Cystic Fibrosis (CF) ages 7 and above. The second drug is named Tobramycin Inhalation Solution (TIS) and is FDA approved for the treatment of CF patients with *PA*.

Inclusion Criteria

1. Confirmed diagnosis of CF
2. Presence of *PA* in 2 lower respiratory tract cultures in the 12 months prior to screening
3. FEV1 ≥ 25 and $\leq 75\%$ predicted
4. History of 1 hospitalization or 1 course of IV antibiotics for an acute respiratory exacerbation in the 12 months prior to screening

Exclusion Criteria

1. Concurrent use of oral, IV or inhaled antibiotics at enrollment
2. Concurrent hospitalization at enrollment
3. History of local or systemic hypersensitivity to monobactams or aminoglycoside antibiotics or history of aminoglycoside antibiotic associated toxicity